Citation:

Jenkins DJA, Wong JMW, Kendall CWC, Esfahani A, Ng VWY, Leong TCK, Faulkner DA, Vidgen E, Greaves KA, Paul G, Singer W. The effect of a plant-based low-carbohydrate ("Eco-Atkins") diet on body weight and blood lipid concentrations in hyperlipidemic subjects. *Arch Intern Med.* 2009;169(11):1046-1054.

PubMed ID: 19506174

Study Design:

Randomized Controlled Trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To determine the effect of a low-carbohydrate weight-loss diet, without the use of animal products, on serum lipid concentrations compared with a higher carbohydrate diet.

Inclusion Criteria:

- Healthy men and postmenopausal women between the ages of 21 and 70 years
- High-normal or raised LDL-C concentration (>131 mg/dL) at diagnosis
- Triglyceride concentration higher than 44 mg/dL but lower than 442 mg/dL
- Body mass index (BMI) higher than 27
- Not currently involved in a weight-loss program

Exclusion Criteria:

- Lipid-lowering medications
- Hormone therapy
- Alcohol consumption of more than 2 drinks/d
- Tobacco use
- Major cardiovascular event or surgery in the preceding six months
- Diabetes
- Untreated hypothyroidism
- Blood pressure (BP) higher than 140/90 mm Hg
- Renal or liver disease
- Cancer (excluding non-melanoma skin cancer)
- Food allergies

Description of Study Protocol:

Recruitment

Participants were recruited through newspaper advertisement and hospital clinic notices.

Design: Randomized controlled trial

Participants were randomized into the high-or low-carbohydrate, calorie reduced diet groups stratified by sex. The study lasted 1 month and was metabolically controlled with all food provided. Participants were seen at weekly intervals over four weeks.

Blinding used (if applicable): implied with measurements

Intervention (if applicable)

- At each visit, fasting body weights and BP were obtained.
- Serum samples were obtained after 12-hour overnight fasts before treatment and at the end of the weeks 2 and 4.
- Body weights and BP were all measured per protocol.
- Food to be eaten by the participants for the entire metabolic month was prepacked and delivered to participants. A "no starch" high- protein nut bread was obtained from the clinic at weekly intervals by the participants.
- Participants were asked to hold exercise constant over the metabolic period. Exercise diaries were completed weekly including the type, duration and intensity of exercise according to the Center for Disease Control and Prevention and the American College of Sports Medicine. Exercise was calculated as metabolic equivalent of tasks (METs).
- Body fat was measured by bioelectrical impedance and waist and hip measurements were measured bi-weekly according to protocol.
- Overall feeling of satiety for the previous week at each study period was measured using a 9-point bipolar semantic scale.

Statistical Analysis

- Results are expressed as mean and standard deviation (SD) for baseline and for study measurements of calories, calorie compliance, carbohydrate, fat, protein, alcohol, fiber and cholesterol intake.
- Differences between group in baseline variables were assessed by 2-sample t test.
- Intention-to-treat (ITT) analysis was undertaken with baseline observation carried forward for subjects who dropped out.
- Within treatment groups, serum lipid concentrations and other measurements were not found to be significantly different between weeks 2 and 4 during the metabolic phase, therefore respective differences were assessed using all available data and reported as changes from baseline to weeks 2 and 4. Change from baseline was the response variable with week as the main effect and baseline as covariate, except when percentage changes from baseline were assessed. A significant difference was found between weeks 2 and 4 for body weight and BMI therefore the end of treatment values were assessed with baseline observation carried forward.
- Dietary data were analyzed using the 2 -sample t tests from mean differences between the 2 treatment diets and at baseline.

Data Collection Summary:

Timing of Measurements

Baseline and at weekly intervals for one month.

Dependent Variables

- Body weight, kg
- BMI
- Body fat, %
- HOMA-IR
- Satiety level (-4 to 4)
- Blood pressure, mm Hg
- Serum total cholesterol (TC), mg/dL
- LDL-cholesterol, mg/dL
- HDL-cholesterol, mg/dL
- Triglycerides, mg/dL
- Ratio TC to HDL-C
- Ratio LDL-C to HDL-C
- Apo AI, mg/dL
- Apo B, mg/dL
- Apo B-apo-AI ratio
- hs-CRP, mg/dL
- Mean calorie intake, kcal
- Total calories, % (SE)
- Carbohydrate
- Protein
- Vegetable protein
- Soy protein
- Saturated fat
- Monounsaturated fat
- Polyunsaturated fat
- Alcohol
- Dietary fiber g/1000 kcal
- Dietary cholesterol mg/1000 kcal

Independent Variables

- Low-carbohydrate, reduced calorie diet
- High-carbohydrate, reduced calorie diet

Control Variables

Description of Actual Data Sample:

Initial N: 47

Attrition (final N): 44 (18 men). Low carbohydrate diet n=22, high-carbohydrate diet n=22

Age: High carbohydrate diet: mean age 56.1 (7.5), low-carbohydrate diet: mean age 57.8 (7.1) p=0.41

Ethnicity European origin, n=32, Saharan Africa, n=4, Indian subcontinent, n=2, Middle Eastern, n=2, 4 subjects did not provide ethnic backgrounds.

Other relevant demographics:

Anthropometrics No differences between groups at baseline.

Location: Toronto, Canada

Summary of Results:

Key Findings

- Weight loss was similar for both groups (approximately 4 kg)
- LDL-C concentration and total cholesterol to HDL-C and apolipoprotein B to apolipoprotein AI ratios were greater for the low-carbohydrate compared with the high-carbohydrate diet (-8.1% [p=0.002]. -8.7% [p=0.004], respectively)
- Reductions in systolic and diastolic blood pressure were also seen (-1.9% [p=0.052] and -2.4% [p=0.02] respectively).
- Mean absolute satiety ratings were significantly higher for the low-carbohydrate diet (1.5[0.3] [low-carbohydrate diet] vs 0.8 [0.3] [high-carbohydrate diet]; p=0.003).
- Satiety scores were positive for both treatments, indicating that the diets tended to satisfy participants.

Effect of High- and Low- Carbohydrate Diets on Body Weight and on Blood Lipid, Apolipoprotein, and C-Reactive Protein Concentrations (Intention-to-Treat Analysis)

	High-Carbohydrate Diet			Low-Carbohydrate Diet			P value
	Week 0	Week 2	Week 4	Week 0	Week 2	Week 4	
Body weight, kg	86.6	83.9	82.3	82.4	80.1	78.5	0.96
BMI	31.0	30.0	29.5	30.6	29.8	29.2	0.91
Body fat %	36.2	....	34.6	36.5	....	35.0	0.95
HOMA-IR	1.7	1.1	1.0	1.5	0.9	1.0	0.85
Satiety (-4 to 4)	1.1	0.9	0.8	1.3	1.6	1.4	0.003
Cholesterol, mg/dL							
Total	254	221	222	257	202	205	0.001
LDL-C	168	147	146	172	134	136	0.002
HDL-C	50	46	47	48	46	46	0.68
Triglycerides, mg/dL	187	138	147	189	113	113	0.002
Ratios							
TC-HDL-C	5.37	4.92	4.94	5.64	4.63	4.64	0.03
LDL-C-HDL-C	3.52	3.27	3.24	3.77	3.10	3.12	0.02
Apolipoproteins							
apo AI, mg/dL	162	146	147	158	146	146	0.71

apo B, mg/dL	137	118	118	139	108	108	0.001
apo B-apo AI ratio	0.86	0.83	0.81	0.89	0.76	0.76	0.003
hs-CRP, mg/dL	2.13	1.22	1.44	2.70	1.87	1.81	0.66

Author Conclusion:

The low-carbohydrate plant-based diet has lipid-lowering advantages over a high-carbohydrate, low-fat weight-loss diet in improving heart disease risk factors not seen with conventional low-fat diets with animal products. Body weight was reduced however the weight loss was likely to result from the calorie deficit rather than metabolic changes associated with an altered macronutrient profile of the diet.

Reviewer Comments:

- *Control diet was a high carbohydrate diet - a "healthy carbohydrate intake" diet would have been useful as the control.*
- *Small number of participants*
- *Some participants were on medications for hypertension and/or hypothyroidism*
- *Study only 4 weeks long*
- *Funding did not play a role in design or conducting the research, collection or analysis of data, preparation, review or approval of the manuscript, however some authors were employed by the funding agency.*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	**Was the research question clearly stated?**	Yes

1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	???
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	???
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes

4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	No
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	???
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	???
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes

7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	Yes
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	???
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	No
10.	**Is bias due to study's funding or sponsorship unlikely?**	???
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	???